UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

JOHN MILAN, by and through his Attorney-in-Fact, SANDRA LEE BOYD,

NOTICE OF REMOVAL OF CIVIL ACTION

Electronically Filed

Plaintiff,

v.

Case No. 2:21-cv-1764

SHENANGO PRESBYTERIAN SENIORCARE d/b/a SHENANGO ON THE GREEN; PRESBYTERIAN SENIORCARE; and CAROLINE DEAUGUSTINE, NHA,

Defendants.

NOTICE OF REMOVAL

Please take notice that Defendant, Shenango Presbyterian Seniorcare d/b/a Shenango on the Green, hereby removes this case from the Court of Common Pleas of Lawrence County to the United State District Court for the Western District of Pennsylvania pursuant to 28 U.S.C. § 1331, § 1441, § 1442, §1446, the Public Readiness and Emergency Preparedness Act, 42 U.S.C. §§ 247d-6d, 247d-6e (2005) (the "PREP Act"), and the Declaration for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15198-01 (March 17, 2020) (including all amendments thereto), and further states:

1. On or about November 2, 2021, Plaintiffs, John Milan, by and through his Attorney-in-Fact, Sandra Lee Boyd, filed a Complaint in the Court of Common Pleas of Lawrence County in a matter styled John Milan, by and through his Attorney-in-Fact, Sandra Lee Boyd, Plaintiff v. Shenango Presbyterian Seniorcare d/b/a Shenango on the Green, Presbyterian Seniorcare, and

<u>Caroline DeAugustine, NHA</u>, Case No. 2021-30007. A true and correct copy of Plaintiffs' Complaint and Jury Demand is attached hereto as Exhibit A.

- 2. Defendant's removal is timely under 28 U.S.C. § 1446(b) as it is being filed within 30 days of service of the Complaint upon this Defendant on November 5, 2021.
- 3. In accordance with 28 U.S.C. §1446(a), a true and correct copy of all of the process and pleadings filed in the action to date, along with a copy of the Civil Docket Sheet, are collectively attached to this notice as Exhibit B (in addition to the Complaint, which is Exhibit A).
- 4. As required by 28 U.S.C. §1446(d), concurrent with this filing, Defendant is filing a true and correct copy of this Notice of Removal with the Clerk of the Court of Common Pleas of Lawrence County, Pennsylvania. A true and correct copy of the Notice of Filing the Notice of Removal is attached hereto as Exhibit C.
- 5. This Notice of Removal is being filed in the United States District for the Western District of Pennsylvania, the District Court of the United States within which the state court action is pending, as required by 28 U.S.C. §§1441(a) and 1446(a).
- 6. Defendants, Presbyterian Seniorcare and Caroline DeAugustine, NHA, are also represented by the undersigned counsel and consent to this removal.
- 7. Accordingly, Defendant has satisfied all procedural requirements governing removal pursuant to 28 U.S.C. §§ 1441 and 1446, the Federal Rules of Civil Procedure, and the Local Rules of this Court.
- 8. By filing this Notice of Removal, Defendant does not waive any defenses that may be available to it under state or federal law.

I. PLAINTIFFS' ALLEGATIONS AND CLAIMS IN THE COMPLAINT

- 9. Plaintiffs' Complaint alleges that Plaintiff, John Milan, was exposed to and infected with COVID-19 while residing at Shenango Presbyterian Seniorcare d/b/a Shenango on the Green (hereinafter "Defendant" or "Shenango" or "the Facility"). See Exhibit A, generally, and at ¶¶ 47-55, 88(a), (o), (r), (s), (v), (z) and (aa), 91, and 92.
- 10. Plaintiffs' claims arise from Defendant's response to the COVID-19 pandemic and their infection control measures and other countermeasures in an attempt to prevent or mitigate the spread of COVID-19.
- 11. Plaintiffs allege that, in Defendant's management and operation of a COVID-19 countermeasure and facility, they failed to protect Mr. Milan from the COVID-19 virus during the pandemic by virtue of the manner in which they used, provided, administered, and utilized infection control and prevention procedures that were designated countermeasures to combat the COVID-19 outbreak. See Exhibit A, generally, and at ¶ 81(a), 81(m) 88(b), 88(i), 88(aa), 90, 91, 92.

II. FEDERAL QUESTION JURSIDCTION EXISTS UNDER 28 U.S.C. § 1331 BY VIRTUE OF COMPLETE PREEMPTION UNDER THE PREP ACT.

12. This case is removable under 28 U.S.C. § 1441(a) on the basis of "original jurisdiction" because Plaintiffs' Complaint asserts claims "arising under" federal law within the meaning of § 1331, as Plaintiffs' allegations invoke the exclusive federal jurisdiction of the Court and the immunities from suit and liability promised in the PREP Act. See 42 U.S.C. § 247d-6d(e) (exclusive federal cause of action and exclusive federal jurisdiction for claims arising from the alleged administration and use of a COVID-19 countermeasure), (a)(1) and (b)(8) (immunity from suit and liability under state and federal law, and preemption of state law)).

A. The PREP Act Provides for Complete Preemption

13. "When [a] federal statute completely preempts [a] state-law cause of action, a claim which comes within the scope of that cause of action, even if pleaded in terms of state law, is in reality based on federal law." See Beneficial Nat. Bank v. Anderson, 539 U.S. 1, 8 (2003). Beneficial provides that state claims may be removed to federal court in two circumstances: (1) when Congress expressly provides; or (2) when a federal statute wholly displaces the state-law cause of action. Id. The PREP Act wholly displaces state-law causes of action for claims related to a covered person's use, misuse, nonuse or allocation of countermeasures to combat a pandemic by creating an exclusive federal remedy for those claims involving both an administrative and judicial component. 42 U.S.C. §247d-6e; §247d-6d(d)(e). This remedial structure was purposefully established by Congress and is explicitly "exclusive of any other civil action or proceeding for any claim or suit [the PREP Act] encompasses" 42 U.S.C. §247d-6e(d). Accordingly, Plaintiffs' allegations of state law causes of action clearly bring her claims within the purview of the PREP Act and mandate complete preemption. See Memorandum Rulings in Rachal v. Natchitoches Nursing & Rehab Center LLC, Civil Docket No. 1:21-CV-00334 (W.D. La. April 30, 2021), at fn. 3, discussed infra; see also Order Regarding Plaintiffs' Motion to Remand and Defendant's Motion to Dismiss the Complaint in Garcia v. Welltower OpCo Group, LLC, No. 8:20-cv-02250-JVS-KESx (C.D. Cal. Feb. 10, 2021), at p. 10, discussed infra.

1. Prep Act Application to the COVID-19 Pandemic

14. The PREP Act, which is a component of the Public Health Services Act ("PHSA"), 42 U.S.C. § 201, et seq., grants healthcare providers and other covered persons immunity from claims for injuries related to the use of approved countermeasures to combat a national public health emergency, such as the COVID-19 pandemic. Congress's goal was to enable healthcare

providers, including nursing facilities, to focus on using every available means to combat a pandemic and save lives without being chilled in their efforts by the threat of lawsuits. 42 U.S.C. § 247d-6d.

- 15. The PREP Act is triggered when the Department of Health and Human Services ("HHS") Secretary issues a declaration defining the scope and breadth of PREP Act protections relevant to a particular public health emergency. *See* 42 U.S.C. § 247d. The PREP Act provides that when a "disease or other health condition or other threat to health constitutes a public health emergency," the Secretary of Health and Human Services (HHS) may issue a declaration "recommending[] . . . the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures" against the disease. <u>Id.</u> When such a declaration issues, "covered persons" who administer or use "covered countermeasures" become "immune from suit and liability under Federal and State law with respect to *all claims for loss caused by, arising out of, relating to, or resulting from* the administration to or the use by an individual of a covered countermeasure" as defined by the Secretary of HHS. 42 U.S.C. § 247d-6d(a)(1) (emphasis added).
- 16. A "covered person" includes a person or entity that "is a qualified person" or a "program planner". 42 U.S.C. § 247d–6d(i)(2)(B). A "qualified person" is defined as a "licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed." 42 U.S.C. § 247d–6d(i)(2)(B)(iv). A "program planner" is defined as "a State or local government, including . . . a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance,

or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b)." 42 U.S.C. § 247d–6d(i)(6). Further, the PREP Act defines a "person" as "an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state or local government agency or department." 42 U.S.C. § 247d–6d(i)(5).

- 17. Congress also explicitly wrote preemption into the PREP Act, stating that "no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that is different from, or is in conflict with, any requirement applicable under this section" and relates to, among other things, use or administration of the covered countermeasure. 42 U.S.C. § 247d-6d(b)(8)(A)-(B).
- In addition, Congress provides two exclusive federal remedies in the PREP Act for individuals with claims for loss arising out of the use of covered countermeasures. First, the Act creates a "Covered Countermeasure Process Fund" for purposes of "providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a). Claimants can receive compensation from this fund by applying for benefits through the Countermeasures Injury Compensation Program. See 42 C.F.R. §§ 110.1-110.100. Second, an injured person may bring "an exclusive Federal cause of action" under the PREP Act "against a covered person for death or serious physical injury proximately caused by willful misconduct." 42 U.S.C. § 247d-6d(d)(1).
- 19. The PREP Act sets forth specific procedures that govern lawsuits asserting this cause of action. <u>Id.</u> at § 247d-6d(e). Pursuant to subsection (e)(1), titled "Exclusive Federal Jurisdiction," any action for willful misconduct must be filed in the U.S. District Court for the District of Columbia. Such claims are also subject to heightened pleading requirements (i.e.,

requirement that claims are to be plead with particularity) and verification of and submission of a physician declaration in support of the complaint; and are assigned to a three- judge panel which has jurisdiction to consider motions to dismiss and motions for summary judgment. 42 U.S.C. § 247d-6d(e)(l), (e)(3) (e)(4) and (e)(5). Moreover, pursuant to Section 247d-6d(e)(l0),

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or motion for summary judgment based on an assertion for the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(S).

- 20. The PREP Act was triggered for COVID-19 when the HHS Secretary issued a declaration on March 17, 2020, announcing that, as of February 4, 2020, "[1]iability immunity as prescribed in the PREP Act. . . is in effect" for any "[a]ctivities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency" related to COVID-19. Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,201-02 (Mar. 17, 2020), amended by 85 Fed. Reg. 21,012 (Apr. 15, 2020) (the "Declaration").
- 21. In that Declaration, the term "administration" is defined, extending beyond the physical distribution of COVID-19 countermeasures to the "management and operation of countermeasure programs as well as the management and operation of locations for [the] purpose of distributing and dispensing countermeasures." See 85 Fed. Reg. 15202.
 - 22. The Declaration also broadly defines "covered countermeasure" as:

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product. Covered

Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

85 Fed. Reg. 15198.

- 23. The Declaration was subsequently amended to add respiratory protective devices to the list of covered countermeasures. See 85 Fed. Reg. 21012, 21013. On June 8, 2020, the Declaration was amended again to reflect HHS's initial intent to "identify the full range of qualified countermeasures" as permitted under the PREP Act. 85 Fed. Reg. 35100, 35101.
- 24. HHS also issued an Advisory Opinion regarding the Declaration on April 17, 2020, recognizing the broad, preemptive nature of the Declaration. See Exhibit D. The Opinion states that "immunity covers claims for loss sounding in tort or contract" and "PREP Act immunity must be read in light of the PREP Act's broad, express-preemption provision." Id. at p. 2.
- 25. On August 14 and August 31, 2020, two additional opinion letters were issued by HHS that: (a) unequivocally confirm that senior living communities, such as Defendant Shenango, are "covered persons" that may be immunized under the PREP Act by virtue of their status as both "program planners" and "qualified persons"; and (b) verify that COVID testing in nursing homes are a covered countermeasure triggering the Act. <u>See</u> Exhibits E and F, respectively.
- 26. Additionally, on October 23, 2020, HHS issued "Advisory Opinion 20-04 on the Public Readiness and Emergency Preparedness Act and Secretary's Declaration Under the Act," confirming that "administration" under the PREP Act is much broader than the mere physical

The Secretary issued an Amended Declaration under the PREP Act, which was effective as of March 27, 2020. The Amendment added respiratory protective devices approved by NIOSH (National Institute for Occupational Safety and Health) as a covered countermeasure under the PREP Act. On June 4, 2020, the Secretary further amended the March 10, 2020 Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. This Amendment was effective as of February 4, 2020. See 85 FR 21012.

provision of a countermeasure to a recipient and encompasses activities related to the "management and operation" of COVID-19 countermeasure programs and those facilities that provide countermeasures to recipients. See Exhibit G. This Advisory Opinion flatly rejects as "wrong" a pre-pandemic New York trial court ruling in Casabianca v. Mt. Sinai Medical Center, 2014 WL 10413521 (New York Co. 12/12/14), that the PREP Act requires the "direct physical" administration of a COVID-19 countermeasure and that the Act is not applicable to claims involving an omission or failure to act.

- 27. Further, on December 3, 2020, the HHS Secretary issued the Fourth Amendment to the Declaration ("Amendment Four") (published at 85 Fed. Reg. 79190 (Dec. 9, 2020)), which, *inter alia*:
 - a. Expressly adopts all COVID-19 Advisory Opinions into its initiating Declaration, giving those directives controlling authority over interpretations of the PREP Act; *Id.* at 79191, 79192, 79194-95;
 - b. Declares that an omission to administer a covered countermeasure can fall within the PREP Act's protections; *Id.* at 79191, 79194, 79197; and
 - c. Makes explicit that cases involving COVID-19 covered countermeasures are to be in the federal system provided by Congress and that this "federal jurisdiction" is essential to the uniform provision of a national response to the COVID-19 pandemic; *Id.* at 79194, 79196, 79197-98.

See Exhibit H.

28. Amendment Four also addresses HHS's authority to define the application of the PREP Act by stating: "42 U.S.C. 247d-6d(b)(7) provides that '[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection." See Amendment Four, at 26 n.25. Where Congress has expressly delegated interpretative authority to an agency, that agency's interpretative

proclamations are controlling on the federal courts. <u>Chevron, Inc. v. NRDC, Inc.</u>, 467 U.S. 837, 843-44 (1984).

- Counsel addressing questions raised by the Fourth Amendment. *See* Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision, Jan. 8, 2021 ("AO 21-01), attached hereto as Exhibit I. AO 21-01 confirms that the PREP Act is indeed invoked by allegations that include not only "use" or administration of countermeasures, but alleged failure to act or inaction, where the non-use was the result of conscious decision-making. See Rachal, supra, at p. 12 (concluding that "HHS's interpretation of the PREP Act and its scope [as set forth in AO 21-01] is reasonable" and, moreover, warrants deference given: "(i) the PREP Act's broad grant of authority to the HHS Secretary; (ii) the Secretary's express incorporation of the OGC's Advisory Opinions into the Declarations for purposes of construing the PREP Act; (iii) the complexity of the relevant statutory provisions; (iv) the technical nature of the subject matter; and (v) the need for uniformity in the judiciary's interpretation of the PREP Act across the United States.").
- 30. AO 21-01 also states that "[t]he PREP Act is a 'Complete Preemption' Statute," because it establishes both a federal and administrative cause of action as the only viable claim and vests exclusive jurisdiction in federal court. <u>Id.</u> at 2.

2. Congress Explicitly Provided for Complete Preemption Under Beneficial

31. Congress intended to regulate national responses to pandemics. The PREP Act expressly satisfies the <u>Beneficial</u> test of preemption in stating that "a covered person shall be *immune from suit and liability* under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an

individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure." §247d-6d(a)(1) (emphasis added); *see also* (b)(8) ("during...a declaration...no State...may establish, enforce, or continue in effect any provision of law or legal requirement that - is different from...any requirement applicable under this section"). The PREP Act further provides that this immunity "applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure . . . or use of such countermeasure." § 247d-6d(a)(2)(B). HHS has instructed time and again that this preemption is to be given the broadest possible application.²

32. Significantly, the PREP Act also provides an extensive claims and litigation process for COVID-19 claimants in accordance the directives of <u>Beneficial</u> by providing for federal redress and displacing state-law liability. Specifically, the PREP Act establishes a prelitigation no-fault monetary fund for those injured by the use or administration of covered countermeasures that must be exhausted prior to relief under the federal civil claims process (§247d-6e(a), (d)(1)), requiring an exclusive federal remedy for all claims related to countermeasures (§247d-6e(d)(5)), and providing a Federal cause of action as the single exception to immunity (§247d-6d(d)(1)).

3. The New Administration Reaffirms PREP Act Provides Complete Preemption

33. Consistently, the new Administration in 2021 reaffirmed that the PREP Act provides for complete preemption of COVID-19 state law claims. On January 28, 2021, HHS amended the Declaration for the fifth time again asserting that HHS Advisory Opinions are

HHS refers *eight times* to the broad applicability of preemption of state law claims. <u>See</u> Advisory Opinion 21-01 (Jan. 8, 2021), at p. 1, Advisory Opinion 20-04 (Oct. 23, 2020), Advisory Opinion 20-02 (May 19, 2020), at p. 4–5, Advisory Opinion 20-01 (Jan. 8, 2020), at p. 2, and six times to the broad applicability of immunity from state law claims. <u>See</u> Advisory Opinion 20-04 (Oct. 23, 2020), at p. 1–2, and Advisory Opinion 20-01 (Jan. 8, 2020), at p. 2, 4, 7.

incorporated into the original Declaration. <u>See</u> Fifth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration, (Jan. 28, 2021), 86 Fed. Reg. 7872, 7874, attached hereto as Exhibit J (stating "[t]he plain language of the PREP Act makes clear that there is complete preemption of state law.").

- 34. There have also been two additional amendments further confirming that the preemptive effect of the PREP Act, with the sixth on February 16, 2021 and the seventh on March 16, 2021.³
- 35. In addition to these HHS authorities, the U.S. Department of Justice ("DOJ") filed a Statement of Interest ("SOI") of the United States in Bolton v. Gallatin Center for Rehabilitation & Healing, LLC, No. 3:30-cv-00683 (M.D. Tenn. Jan. 19, 2021) at Docket No. 35, which constitutes the official position of the United States' interest in the enforcement of the PREP Act, stating, *inter alia*, that the PREP Act "completely preempts claims relating to the administration or use of covered countermeasures with respect to a public health emergency." See Exhibit K, at 1, 7-8. Further, it states that the two key provisions of the PREP Act the immunity provision for all Federal and state law claims, and the exclusive alternative remedy provision, established as the sole exception to immunity operate together to demonstrate the PREP Act's completely preemptive nature. Id. at 7–8. The DOJ also noted that the PREP Act is crucial to the "whole-of-nation response" to public health emergencies (which depends on cooperation among private-sector partners and state and local officials across the nation) and "sweeping" immunity was granted to encourage such cooperation. Id. at 1-2.

³ See 86 Fed. Reg. 9516 (Feb. 16, 2021), and 86 (Fed. Reg. 14462 (Mar. 16, 2021).

36. On February 10, 2021, the U.S. District Court for the Central District of California specifically invoked AO 21-01 to deny a motion for remand in an action against a nursing home which alleged failure to adequately use Personal Protective Equipment ("PPE") and COVID countermeasures, holding that "because the OGC stated that the PREP Act is a complete preemption statute ... an adequate basis for federal question jurisdiction exists." See Garcia v. Welltower OpCo Group LLC, No. 8:20-cv-02250-JVS-KESx, 2021 U.S.Dist. LEXIS 25738, at *24 (C.D. Cal. Feb. 10, 2021), attached hereto as Exhibit L. The Court further found that the allegations of the complaint fell squarely within the scope of the PREP Act:

Plaintiffs' injuries "aris[e] out of, relat[e] to, or result[] from the administration to or the use by an individual of a covered countermeasure." See 42 U.S.C. § 247d-6d(a)(1). For example, the FAC details infection control measures and procedures including symptom checking, staff monitoring and screening, and limiting visitationIn other places, the FAC directly draws upon the use (and in some case, misuse) of PPE The FAC also details screening measures employed by [Defendants] related to certain professional services provided within the facility. These allegations of use and misuse of PPE and the infection control measures directly relate to covered countermeasures within the meaning of the PREP Act.

<u>Id.</u>, at *21.

37. Additionally, the District Court for the Western District of Louisiana likewise agreed that the PREP Act is a complete preemption statute, finding that the PREP Act confers federal jurisdiction and completely preempts claims falling within its scope because it includes: a civil enforcement provision that creates a cause of action that both replaces and protects the analogous area of state law; a specific jurisdictional grant to the federal courts for enforcement of the right; and a clear Congressional intent that claims brought under the federal law be exclusive.

See Rachal, supra, attached hereto as Exhibit M, at fn. 3.

B. Plaintiffs' Claims Fall Within the Purview of the PREP Act

- 38. Here, based on the face of the Complaint, the totality of the allegations made therein and the logical impact of its most central allegations, the PREP Act is implicated by Plaintiffs' claims against Removing Defendant Shenango as a "covered person" engaged in "recommended activities" under the Act. 42 U.S.C.A. §247d–6d(a)(1).
- 39. Defendant is a "covered persons" as contemplated by 42 U.S.C. § 247d–6d and as confirmed by the August 14, 2020 HHS Advisory Opinion in that it is both a "qualified person" and "program planner" under 42 U.S.C.A. § 247d-6d(i)(2)(B). Removing Defendant was acting as a "qualified person" because it is a healthcare provider authorized to administer and/or use FDA approved medical devices, such as face masks, to prevent or mitigate the spread of COVID-19. 42 U.S.C. § 247d-6d(i)(8). Defendant was also acting as a "program planner" that managed, supervised and administered the infection control and COVID-19 specific programs in the treatment of COVID-19 residents, under which covered countermeasures, including, but not limited to, the use of face masks and other personal protective equipment, visitation restrictions, infection control procedures, testing, and screening requirements, at the facility in an effort to prevent and mitigate the spread of COVID-19 to its residents during the pandemic. See Rachal, supra, at pp. 9-10 (finding nursing homes are "covered persons" under the PREP Act).
- 40. Plaintiffs have alleged claims involving a "covered activity" relative to a "covered countermeasure." Specifically, Plaintiffs fault Defendant for the manner in which they used, administered, and allocated COVID-19 countermeasures as part of their infection control program and further allege that, as result of this decision making, Mr. Milan became infected with COVID-19 during his residency. See Exhibit A, generally, and at ¶¶ 81(a), 81(m) 88(b), 88(i), 88(aa), 90, 91, 92. Plaintiffs assert the negligent "operation and management" of a COVID-19 countermeasure

plan, coupled with the alleged negligent "operation and management" of a COVID-19 countermeasure facility to include infection control procedures. These allegations cause this action to fall squarely under the definition of use and "administration" thereby invoking the PREP Act. See id., generally, and at ¶ 25, 81(a), 81(m) 88(b), 88(i), 88(aa), 90, 91, 92.

- 41. Additionally, while Defendant respectfully asserts that the PREP Act completely preempts all claims arising from or relating to the use of a covered countermeasure, Plaintiffs' allegations are completely preempted by the PREP Act under the "willful misconduct" standard outlined by the Third Circuit in Maglioli v. Alliance HC Holdings, LC, Nos. 20-2833, 20-2834, 2021 WL 4890189 (3d Cir. Oct. 20, 2021). As noted in Maglioli, pursuant to 42 U.S.C.A. § 247d-6d(d)(1), the PREP Act provides "an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct." According to the Maglioli Court, the PREP Act "unambiguously" creates an exclusive cause of action for willful misconduct, thereby establishing original federal jurisdiction over such claims allowing removal jurisdiction under 28 U.S.C. §§ 1331 and 1442. Maglioli at *7 (citing 42 U.S.C. §§ 247d-6d, 247d-6e).
- 42. Plaintiffs' Complaint unequivocally alleges willful and intentional misconduct in the care and treatment of Mr. Milan. A review of Plaintiffs' Complaint clearly demonstrates that the allegations set forth therein are all claims that the Shenango acted willfully in bringing about harm to Mr. Milan. Specifically, Plaintiffs' Complaint pleads the following allegations:
 - 87. The corporate conduct of the Defendants was independent of the negligent conduct of the employees of the Facility, and was outrageous, **willful**, and wanton, and exhibited a reckless indifference to the health and well-being of the residents, including John Milan.

There is now a pending Petition for Rehearing En Banc in the <u>Maglioli</u> case, which asserts that the Third Circuit was wrong to find only "partial complete preemption" by the PREP Act. *See* <u>Maglioli</u>, Case No. 2:20-cv-06605-KM-ESK, at ECF No. 80.

- 92. Despite a history of poor infection control, the Defendants recklessly and **willfully** allowed these practices to continue and failed to follow safety protocols to prevent Covid-19 from spreading through the Facility thereby resulting in Mr. Milan needlessly contracting the virus, among the other injuries described herein.
- 106. The conduct of the Defendants was intentional, outrageous, **willful** and wanton, and exhibited a reckless indifference to the health and well-being of John Milan.

See Exhibit A at ¶¶ 87, 92, 106 (emphasis added).

- 43. Furthermore, looking at the Complaint as a whole, Plaintiffs' allegations meet the definition of "willful misconduct," even where Plaintiffs do not specifically include the term "willful" in the pleading.
- 44. The term "willful misconduct" means "an act or omission that is take (i) intentionally to achieve a wrongful purpose; (ii) **knowingly** without legal or factual justification; and (iii) in **disregard of a known or obvious risk** that is so great as to make it highly probable that the harm will outweigh the benefit." 42 U.S.C. § 247d-6d(c)(1)(A). "The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness." <u>Id.</u> § 247d-6d(c)(1)(B).
- 45. Here, Plaintiffs allege that Defendants "**knowingly** sacrificed the quality of care received by all residents, including John Milan, by failing to manage, care, monitor, document, chart, prevent, diagnose and/or treat the injuries and illnesses suffered by John Milan, as described herein, which included suffering from Covid-19. . ." Exhibit A at ¶ 36.
- 46. Plaintiffs further allege that Defendants "**made a conscious decision** to operate and/or manage the Facility so as to maximize revenues at the expense of the care required to be provided to their residents, including John Milan." <u>Id.</u> at ¶ 25 (emphasis added). Plaintiffs further allege that Defendants "**intentionally** and/or recklessly mismanaged and/or reduced staffing levels

below the level necessary to provide adequate care to residents," and "under-budgeted" and grossly understaffed" the Facility in order to increase revenue. <u>Id.</u> at ¶¶ 26-34, 71, 81(d) (emphasis added).

- 47. Plaintiff claims the "intentional" understaffing of the Facility caused the damages he seeks relief for in this case, which include his COVID-19 diagnosis. <u>Id.</u> at ¶ 35.
- 48. There is no question that the language of the allegations in the aforementioned paragraphs clearly fall within the definition of willful misconduct. Plaintiffs' claims for willful misconduct unquestionably bring them under the PREP Act and invoke Article III jurisdiction and 28 U.S.C. §1331, 1441. "Congress said the cause of action for willful misconduct is exclusive, so it is." Maglioli, at *9.
- 49. Additionally, the Complaint seeks relief for punitive damages. <u>Id.</u> at ¶ 107; *see also* the *ad damnum* following ¶ 107. Under Pennsylvania law, punitive damages are awardable only for "torts that are committed <u>willfully</u>, maliciously, or so carelessly as to indicate wanton disregard of the rights of the party injured." *Bert Co. v. Turk*, 257 A.3d 93, 119 (Pa. Super. 2021) (internal quotation omitted).
- 50. Defendants of course deny Plaintiffs' salacious and wholly incorrect claims. Nevertheless, Plaintiffs' clear allegations of willful misconduct are within the scope of the PREP Act and completely preempted.

III. FEDERAL QUESTION JURISDICTION ALSO EXISTS PURSUANT TO THE GRABLE DOCTRINE.

- 51. Federal jurisdiction also exists where an action "arises under" federal law and raises a substantial federal issue, actually disputed and substantial. See Grable & Sons Metal Prods. V. Darue Eng'g & Mfg., 545 U.S. 308 (2005).
- 52. HHS, by and through its Fourth Amended Declaration and AO 21-01, also confirms that the PREP Act confers a separate, independent grounds for federal question jurisdiction under

the <u>Grable</u> doctrine. <u>See</u> AO 21-01 at pp. 4–5, discussing <u>Grable</u>, 545 U.S. at 312. The Advisory Opinion states that "ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court." <u>Id.</u> at p. 5. HHS provides that "there are substantial federal legal and policy...interests within the meaning of [the <u>Grable</u> doctrine] in having a unified, whole-of-nation response to the COVID-19 pandemic among federal, state, local, and private-sector entities." <u>Id.</u> (quoting 85 Fed. Reg. at 79, 197).

- 53. HHS further states that: "Congress delegated to [the Secretary] the authority to strike the appropriate Federal-state balance with respect to particular covered countermeasures through PREP Act declarations." HHS's interpretation of <u>Grable</u> is consistent with the Supreme Court's long-standing rule "that in certain cases federal question jurisdiction will lie over state-law claims that implicate federal issues." <u>Grable</u>, 545 U.S. at 312. "The doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." Id.
- 54. The <u>Grable</u> court determined that there is no single test for determining whether an embedded federal issue exists, but that, in general, a two-step process determines whether a state law claim "arises under" federal law: (1) the state law claim must necessarily raise a stated federal issue that is actually disputed and substantial; and (2) federal courts must be able to entertain the state law claims "without disturbing a congressionally approved balance of state and federal judicial responsibilities." 545 U.S. at 314; <u>see also Merrell Dow Pharmaceuticals Inc. v.</u> Thompson, 478 US 804, 808 (1986).
- 55. Here, both prongs are satisfied. First, Plaintiffs bring claims relating to Defendant's alleged use or administration (or misuse, nonuse or non-administration) of covered

countermeasures in connection with the care and treatment of Mr. Milan, which necessarily implicates disputed and substantial federal issues. See § 247d-6d.

- 56. Second, as confirmed by AO 21-01 and the HHS Declaration (and its amendments), the PREP Act expresses a clear intention to supersede and preempt state control of the very issues raised by Plaintiffs, i.e., issues concerning Defendant's conscious decisions as when to use or administer (or not) covered countermeasures, including various infection control measures.
- 57. A substantial and disputed federal issue regarding the application of the PREP Act to Plaintiffs' claims therefore necessarily exists and must be resolved by this Court to ensure the uniform and appropriate application of the PREP Act. The federal legal and policy issues described in the Fourth Amended Declaration and the HHS Advisory Opinions control and authorize this Court to retain this action under <u>Grable</u>.

IV. FEDERAL QUESTION JURSIDCTION EXISTS PURSUANT TO THE FEDERAL OFFICER REMOVAL STATUTE (28 U.S.C. § 1442(a)(1))

- 58. Removal is also proper under 28 U.S.C. § 1442(a)(1), which provides for removal when a defendant is sued for acts undertaken at the direction of a federal officer.
- 59. "[T]he federal officer removal statute [Section 1442(a)] is to be 'broadly construed' in favor of a federal forum." In re Commonwealth's Motion to Appoint Counsel Against or Directed to Def. Ass'n of Phila., 790 F.3d 457, 466 (3d Cir. 2015) (quoting Sun Buick, Inc. v. Saab Cars USA, Inc., 26 F.3d 1259, 1262 (3d Cir. 1994)).
- 60. This case is removable pursuant to Section 1442(a) because: "(1) Defendants are 'persons' within the meaning of the statute; (2) Plaintiffs' claims are based upon Defendant's conduct 'acting under' the United States, its agencies, or its officers as part of the nation's critical infrastructure; (3) Plaintiffs' claims are 'for, or relating to' an act under color of federal office; and (4) Defendants raise a colorable federal defense to the Plaintiffs' claims." Papp v. Fore-Kast Sales

Co., 842 F.3d 805, 811 (3d Cir. 2016). All requirements for removal under § 1442(a)(1) are satisfied here.

61. Defendant Shenango is a "person" under the federal officer removal statute, as it is a corporate entity, and corporations are "person[s]" pursuant to Section 1442(a)(1). Papp, 842 F.3d at 812 (for purposes of Section 1442(a), "a corporation is in legal fact a person" (citing 1 U.S.C. § 1)).

A. Acting under the Direction of a Federal Officer

- 62. Once COVID-19 began to spread, the federal government declared that healthcare providers were "critical infrastructure" businesses that were obligated to aid the federal government in preventing the spread of the virus during this unprecedented national emergency by following the federal government's direction under its close supervision.⁵
- 63. Additionally, on April 19, 2020, the Pennsylvania Department of Health issued a Health Alert, stating "The Centers for Disease Control and Prevention (CDC) issued updated interim guidelines for implementing safety practices for **critical infrastructure workers** who may have had exposure to a person with suspected or confirmed COVID-19. The Pennsylvania Department of Health (DOH) is providing these updated guidelines for life-sustaining business workers."
- 64. Designating their activities as "critical infrastructure" enabled the federal government to enlist the aid of these private parties to ensure the continued operation of the

See Memorandum on Identification of Essential Critical Infrastructure Workers During COVID-19 Response, CISA.gov, available at https://www.cisa.gov/sites/default/files/publications/CISA-Guidance-on-Essential-Critical-Infrastructure-Workers-1-20-508c.pdf (last visited Apr. 28, 2021).

⁶ <u>See</u> Interim Guidelines for Exposed Life-Sustaining Business Workers, available at https://www.health.pa.gov/topics/Documents/HAN/2020-PAHAN-498-04-19-ALT-ALERT_Criti.pdf.

65. During this time of crisis, there has been a nationwide PPE shortage.⁷ FEMA worked closely with businesses designated as "healthcare/public health" critical infrastructure to

available at https://emergency.cdc.gov/han/2020/han00428.asp; CDC Health Advisory dated March 8, 2020, available at https://emergency.cdc.gov/han/2020/han00429.asp; CDC, "Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings," dated 3/31/2020, available at https://web.archive.org/web/20200331043207/https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-

recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2 F2019-ncov%2Fhcp%2Finfection-control.html (archived website); CMS, "Guidance for use of Certain Industrial Respirators by Health Care Personnel," dated 3/10/2020, available at https://www.cms.gov/files/document/qso-20-17-all.pdf; CDC, "Strategies for Optimizing the Supply of Facemasks," dated 3/18/2020, available at http://web.archive.org/web/20200318213323/https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/face-masks.html (archived website).

As is widely known, there has been a scarcity of available PPE and testing supplies on a global level during the pandemic, which has required health care providers to adjust and adapt on a daily basis in an effort to fight the COVID-19 virus. Brighton's COVID-specific programs by necessity included methodology of allocating these scarce countermeasures. During the time frame relevant to the complaint, CDC and CMS issued directives pertaining to the preservation of PPE Health Advisory dated 1/8/2020, testing. See, e.g., CDC https://emergency.cdc.gov/han/han00424.asp; CDC Health Advisory dated 1/17/2020, available at https://emergency.cdc.gov/han/han00426.asp; CDC, Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting, dated 1/24/2020, available https://web.archive.org/web/20200128222452/https://www.cdc.gov/coronavirus/2019ncov/hcp/infection-control.html (archived website); CDC Health Advisory dated Feb 28, 2020,

address the need for PPE and other critical supplies to continue operations in accordance with CDC guidance. Congress also expressly approved and supported the pervasive new role of the federal government in overseeing the operation of "critical infrastructure" skilled nursing homes and assisted living communities by allocating additional funding to such healthcare providers under the CARES Act to accommodate critical ongoing operations in view of the pandemic.

- 66. Also, at the very beginning of the COVID-19 crisis in the United States, the federal government enlisted nursing facilities and assisted living communities in its efforts to fulfill the government's task of ensuring that these facilities could assist in the safe transfer and admission of patients between healthcare facilities during an unprecedented national crisis. In March 2020, it was reported that U.S. hospital beds were already maxed out (prior to COVID-19 hitting the hospitals) limiting healthcare facilities' ability to handle the "presumed" influx of COVID-19 patients.⁸
- 67. Therefore, prior to the COVID-19 pandemic, regulation of skilled nursing and assisted living facilities was very general in nature. However, as a direct result of the COVID-19 global public health crisis and their designation as critical infrastructure, there was a clear and sudden paradigm shift. Thus, since the pandemic began, through the federal directives issued by the CDC, CMS and others, federal authorities have been explicitly guiding operational decisions related to clinical pandemic response in skilled nursing facilities. As just a few examples, facilities were ordered to restrict visitation, cancel communal dining, and implement active screening and staff for fever and respiratory symptoms.⁹

Supply of Facemasks (updated Mar. 17, 2020); CDC, Using Personal Protective Equipment

⁸ U.S. Hospital Beds Were Already Maxed Out Before Coronavirus Pandemic, U.S. News (Mar. 26, 2020) available at https://www.usnews.com/news/health-news/articles/2020-03-26/us-hospital-beds-were-already-maxed-out-before-coronavirus-pandemic (last visited Apr. 28, 2021).

9 <u>E.g.</u>, Ctrs. For Medicare & Medicaid Servs., COVID-19 Long-Term Care Facility Guidance (Apr. 2, 2020); Ctrs. For Disease Control & Prevention, Strategies for Optimizing the

- 68. Facilities were also instructed on, among other things, which patients and staff to test for COVID-19, under what circumstances to use and how to conserve PPE, when to permit staff who had COVID-19 to return to work, how to mitigate staff shortages including when to permit COVID-19 positive but asymptomatic staff to return to work, and how to handle the isolation of residents infected with COVID-19 and those under investigation for COVID-19. These very detailed clinical directives and instructions represented a marked departure from the regulatory structure which existed before the pandemic.
- 69. The United States Supreme Court has held that the phrase "acting under" involves "an effort to assist, or help carry out, the duties or tasks of the federal superior." Watson v. Philip Morris Cos., 551 U.S. 142, 152 (2007); see also In re Commonwealth's Motion to Appoint Counsel Against or Directed to Def. Ass'n of Phila, supra, at 457. The "acting under" requirement is broad and is also to be liberally construed. Watson at 147. Federal courts "have explicitly rejected the notion that a defendant could only be 'acting under' a federal officer if the complained-of conduct was done at the specific behest of the federal officer or agency." Papp v. Fore-Kast Sales Co., 842 F.3d 805, 813 (3rd Cir. 2016). And detailed regulation to compel specific conduct satisfies the second requirement. Winters v. Diamond Shamrock Chem. Co., 149 F.3d. 387 (5th Cir. 1998).
- 70. "[R]emoval by a 'person acting under' a federal officer must be predicated upon a showing that the acts that form the basis for the state civil or criminal suit were performed pursuant to an officer's direct orders or to comprehensive and detailed regulations." <u>Cf. Bakalis v. Crossland Savings Bank</u>, 781 F. Supp. 140, 144-145 (E.D.N.Y. 1991); <u>Ryan v. Dow Chemical Co.</u>, 781

⁽updated Aug 19, 2020); Exec. Order No. 20-009, *In Re: Suspension of Statutes, Rules, and Orders Pursuant to Executive Order Number 20-52, Made Necessary by the COVID-19 Public Health Emergency*; Exec. Order No, 20-52, *Emergency Management-COVID-19 Public Health Emergency*.

F.Supp. 934, 947 (E.D.N.Y. 1992); <u>Fung v. Abex, Corp.</u>, 816 F. Supp. 569, 572 (N.D. Cal. 1992). The "acting under" requirement is met when a defendant is acting pursuant to detailed and ongoing instructions from a federal officer. Winters, supra, 149 F.3d. 387 (5th Cir. 1998).

- 71. Defendant Shenango satisfies the first element for federal officer removal because, as part of the country's critical infrastructure, Defendant acted at all relevant times "to assist, or to help carry out, the duties or tasks of the federal superior," by aiding the federal government in "fulfill[ing] other basic governmental tasks" that otherwise "the Government itself would have had to perform." See Watson, 551 U.S. at 153-54.¹⁰
- 72. The decision in <u>Fields v. Brown</u>, No. 6:20-cv-00475, 2021 WL 510620 (E.D. Tex. Feb. 11, 2021) is persuasive. In pertinent part, the court in <u>Fields</u> held that a Tyson Foods meatpacking facility was "acting under" the direction of a federal officer because Tyson Foods "exhibited 'an effort to help assist, or carry out, the duties and tasks" of the federal government by "working directly with the Department of Agriculture and the [Food Safety and Inspection Service] to guarantee that there was an adequate food supply" during the COVID-19 pandemic. <u>Id.</u> at *3 (citation omitted). In holding that federal officer removal was appropriate, and that the Tyson Foods meatpacking plant did in fact "act[] under" the direction of a federal officer in continuing its meatpacking operations, the court rejected plaintiffs' argument that Tyson Foods merely "communicated with federal regulators and that Tyson Foods was subject to federal regulation." <u>Id.</u> Rather, the court relied on the additional facts plead by Tyson as outcome

Maglioli, supra, which is not yet final and hence not binding, misapplied the Watson test for federal officer jurisdiction largely out of a fear of creating a "slippery slope." Maglioli, supra, at *5. The Court worried that "clergy, farmers, bus drivers" may be deemed federal officers if it recognized nursing facilities as federal officers. Id. However, such institutions do not have Letters or Declarations from HHS declaring them to be "program planners," "covered persons," "qualified persons," or "critical partners" in fighting COVID-19 under the PREP Act like Defendant in this action.

determinative: *inter alia*, ". . . .the critical-infrastructure designation. . ." of Tyson Foods' meatpacking plant, the fact that the "Department of Agriculture and the [Food Safety Inspection Service] closely monitored Tyson Food's meatpacking plants, staffing some employees onsite," and that "Congress even allocated additional funding to [the Food Safety Inspection Service] to ensure that they had the resources to adequately supervise meatpacking plants like that one at issue. . ." <u>Id.</u>

73. Similarly, Shenango was designated as a "critical infrastructure," was closely monitored by the federal government and assisted the government and, as such, Defendant was "acting under" the direction of a federal officer in responding to COVID-19 pandemic.

B. Causal Nexus Exists Between Plaintiffs' Claim and the Actions Taken by Defendant Pursuant to Federal Direction

- 74. The next requirement, often referred to as the "nexus" or "causation" requirement, demands that the alleged conduct have been undertaken "for or relating to" a federal office. To meet this requirement, "it is sufficient for there to be a connection or association between the act in question and the federal office." <u>Defender Ass'n</u>, 790 F.3d at 471.
- 75. There is a clear causal nexus between the claims against Defendant and the actions taken by them in responding to and administering care related to the COVID-19 outbreak. Plaintiffs' Complaint specifically alleges a deficiency in Defendant's actions concerning use of infection control procedures taken in efforts to prevent the spread of COVID-19 within the nursing facilities while responding to constantly evolving governmental directives and working to preserve resources so as to enable a nationwide response. Unquestionably, the nexus element is met as evidenced by the nature of the claims and the various orders, guidelines and recommendations followed by Defendant in responding to the pandemic.

- 76. For example, on March 8, 2020, the CDC noted that with increased access to testing, the criteria for such testing was being expanded to include symptomatic individuals with chronic medical conditions, individuals over the age of 65, and individuals who were in close contact with a laboratory that had a confirmed positive COVID-19 patient. <u>Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19)</u>, CDC, available at https://emergency.cdc.gov/han/2020/HAN00429.asp. Defendant was following explicit guidance issued by the CDC with respect to the testing of its staff and residents, and, as such, were required to only test those individuals who met CDC criteria for doing so.
- 77. On March 17, 2020, the CDC further directed facilities as to when and under what circumstances the use of a facemask or N95 respirator was appropriate, and it also ordered facilities to conserve all types PPE otherwise used in the ordinary course of business given known and ongoing shortages. Strategies for Optimizing the Supply of N95 Respirators, CDC, available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html.
- 78. Defendant was required to follow these directives. As part of the nation's "critical infrastructure," Shenango was acting under the explicit direction of the federal government in implementing its on-site response to the COVID-19 pandemic.

C. Defendant Has a Colorable Defense Based on Federal Law

79. For purposes of removal, Defendant must present a colorable defense based on federal law: the defense must only be "colorable," and need not be "clearly sustainable," as the purpose for the removal statute is to assure that the validity of the defense is tried in federal court. Willingham v. Morgan, 395 U.S. 402, 407 (1969). "[O]ne of the most important reasons for removal is to have the validity of the defense of official immunity tried in a federal court;" for this reason, the Supreme Court has "rejected a narrow, grudging" approach when analyzing whether a

defendant had raised a colorable federal defense. <u>Jefferson Cty. v. Acker</u>, 527 U.S. 423, 431

(1999).

80. Defendant asserts a federal defense in this case - namely, immunity under the PREP

Act for their administration and use of "covered countermeasures." In doing so, Defendant satisfies

the "colorable federal defense" element of the federal officer removal statute. A defendant need

only show it has a plausible federal defense. Ruppel v. CBS Corp., 701 F.3d 1176, 1182 (7th Cir.

2012). See Section II.B., supra.

81. Here, Defendant is immunized under the PREP Act for the conduct about which

Plaintiffs complain, as Defendant acted in accordance with federal directives and guidelines aimed

to protect residents and staff from COVID-19 exposure and prevent the spread of the virus.

WHEREFORE, this action is hereby removed to this Court from the Court of Common

Pleas of Lawrence County, Pennsylvania. Plaintiffs are hereby notified to proceed no further in

state court.

Dated: December 3, 2021

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 3, 2021, a copy of the foregoing Notice of Removal was served, via e-mail, upon the following counsel of record:

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